Extramembranous Placement of an Air-Coupled vs. Transducer-Tipped Intrauterine Pressure Catheter

A Randomized Comparison

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OBJECTIVE: To compare the rate of extramembranous placement between 2 types of intrauterine pressure catheter.

STUDY DESIGN: Women were randomized to a transducer-tipped intrauterine pressure catheter or an air-coupled intrauterine pressure catheter from October 1998 to August 1999. Women were eligible for the study if their attending physicians decided to place an intrauterine pressure catheter. Our primary outcome variable was extramembranous placement. The intrauterine pressure catheter was left in place during cesarean delivery, and the position was documented.

RESULTS: A total of 257 women entered the trial. Eight were excluded due to removal of the catheter before cesarean delivery, leaving 249 evaluable patients. Of those 249, 105 (44.3 %) received cesarean delivery, with 41 in the air-coupled group and 64 in the transducer-tipped group. There were no significant differences in maternal age, gestational age, gravidity, duration of membrane rupture, birth weight, pharmaceutical drug use, cocaine use, oxytocin use or catheter removal due to poor function. The transducer-tipped catheter was placed outside the membranes significantly more frequently than was the air-coupled catheter (12.5% vs. 2.4%, p=0.02).

CONCLUSION: Transducer-tipped catheters were significantly more likely to be placed in the extramembranous space than were air-coupled catheters. (J Reprod Med 2005;50:578–584)

Obstetricians should carefully consider the possible risks of extramembranous placement vs. the benefits of internal contraction monitoring before deciding to monitor, especially with a transducer-tipped catheter.

Keywords: catheter, labor, intrauterine pressure catheters.

The first attempts to measure the expulsive forces of the uterus date to 1861, when Kristeller described uterine expulsive efforts with a dynamometer in the handle of obstetric forceps.[1] This report was followed by multiple reports recording contraction strength and duration by placement of a balloon or bag in the extramembranous space of the lower

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Funded in part by an unrestricted grant from Clinical Innovations.

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Financial Disclosure: The authors have no connection to any companies or products mentioned in this article.

uterine segment.[2-6] In an effort to provide a more direct measurement, the first open, water-filled intrauterine catheter to measure uterine effort was used by Williams and Stallworthy in 1952.[7] In the mid 1980s, a smaller and more reliable microtransducer placed in the tip of an intrauterine pressure catheter designed by Millar came to widely replace the less reliable open water-filled catheters.[8] Placement of intrauterine pressure catheters has become common, with 10–20% of all births in the United States having a catheter placed.[9,10]

While complications had been reported with the early open, water-filled catheters,[11-15] the newer, transducer-tipped catheters were thought to be safer. In 1993, however, 4 cases of placental abruption shortly after placement of a transducer-tipped catheter were reported.[16] In that report, the authors theorized that the stiffness and size of the catheter tip predisposed the catheter to extramembranous/retroplacental placement and resultant placental abruption. This was soon followed by a report by Handwerker and Selick, who observed similar findings in 4 women after the insertion of a transducer-tipped catheter.[17]

The rate of extramembranous placement is unknown but may be higher than initially suspected. By identifying a "blood flash" in the clear tubing of an air-coupled pressure catheter or by injecting dye through the amnioinfusion port of a transducer-tipped catheter, Lind found a 14–38% rate of extramembranous placement.[9,18] In an effort to better define the rate of extramembranous placement and the effect of catheter type on this rate, we designed a randomized trial comparing a transducer-tipped pressure catheter to an air-coupled catheter.

Materials and Methods

After approval from the human experimentation committee and institutional review board at Christiana Hospital and Johns Hopkins Hospital, we performed a randomized trial from October 1998 to August 1999 comparing 2 intrauterine pressure monitoring systems. Randomization was performed via computer and the number sequentially placed in opaque envelopes by a research nurse unfamiliar with the trial. Women who were in labor with ruptured membranes at term were eligible for entry if their attending physicians had made the decision to place an intrauterine pressure catheter. Women with chorioamnionitis, nonvertex presentation, intact membranes, no evidence of labor, vaginal bleeding, history of placental abruption or need for immediate delivery were excluded.

After meeting eligibility requirements, the patients were randomized to 1 of 2 groups: the first used a transducer-tipped intrauterine pressure catheter, and the second used an air-coupled catheter. Women randomized to the transducer-tipped group had an Intran Plus™ (Utah Medical products, Midvale, Utah) placed. Women randomized to the air-coupled group had a Koala™ (Clinical Innovations, Murray, Utah) catheter placed. Because we had not used either of these catheters in either labor and delivery suite prior to the trial, the medical and nursing staffs received 2 formal instruction sessions on the use of each catheter by someone unfamiliar with the trial but experienced with both catheters. Since only physicians were permitted to place intrauterine pressure catheters at our hospitals, the insertion technique was formally reviewed with the resident and attending obstetric staff. A standardized technique modified from the technique recommended by Chan et al[12] was used. The intrauterine pressure catheter was to be placed at the 6 o'clock position between the cervix and fetal head (unless there was a known posterior placenta). If resistance was met, the catheter was to be withdrawn and repositioned 45° from the initial insertion site. Since the location of the placenta had been determined sonographically prior to labor in our patients, we asked the physicians to place the catheter opposite to the reported placental implantation site.

Because the primary outcome variable of this trial was extramembranous placement, we asked that all study catheters be left in place during cesarean delivery and that their position be documented at the time of surgery by the senior surgeon. Blood seen in the clear tubing of the air-coupled catheter was considered to demonstrate extramembranous placement as per Lind and Wallace.[18] This analysis was not possible with the transducer-tipped catheter due to the opaque tubing. A power analysis was performed prior to institution of the trial. Using a 14% rate of extramembranous placement[9] to detect a 20% difference in the rate of such placement and maintain 80% power with an α error of 0.05, a total of 99 women receiving cesarean delivery were required.

Secondary outcome variables included difficult insertion as rated subjectively as yes or no by the inserting physician, presence of bleeding after placement, removal of the catheter for malfunction and color of the fluid in the clear tubing in the air-coupled group.

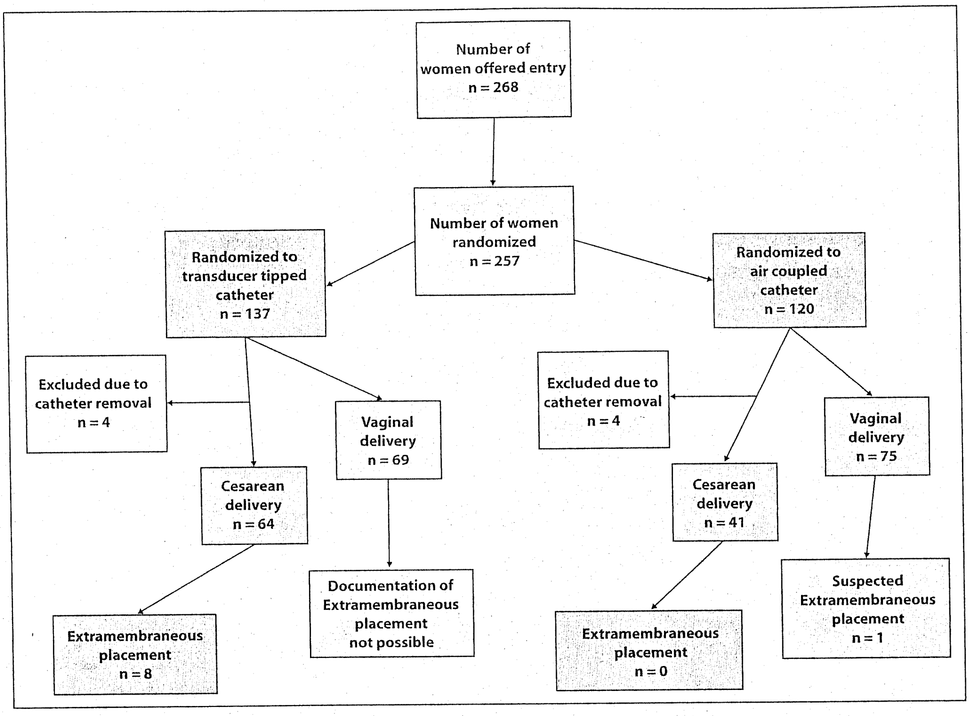

Figure 1 Flow of patients through the trial.

Student's t test, χ^2 analysis, Fisher's exact test and Kruskal-Wallis test were used when appropriate.

Results

A total of 268 women were offered participation; 257 (95.9%) accepted and entered the trial. Patient allocation is described in Figure 1. The trial was conducted from October 1998 to August of 1999. One hundred twenty women were randomized to the air-coupled group and 137 to the transducer-tipped group. The results from these pregnancies were used for analysis of antenatal variables. One hundred thirteen women received cesarean delivery; of them, 8 (4 in the transducer-tipped group and 4 in the air-coupled group) were excluded due to inadvertent removal of the catheter before cesarean delivery. This left 105 evaluable patients for analysis of the primary outcome variable, extramembranous placement. Forty-one women were in the air-coupled group and 64 in the transducer-tipped group. All catheters were placed by a resident or attending physician in obstetrics and gynecology. All women had had sonograms during pregnancy to document the placental position, which guided placement.

Demographic characteristics were not significantly different between the total group of enrolled patients (Table I) and the group who received a cesarean delivery (Table II). Women who received the transducer-tipped catheter showed a trend toward a longer duration of membrane rupture, defined as rupture of membranes until delivery (14.8 vs. 10.2 hours, $p = 0.09$) and were more likely to deliver by cesarean (52.6% vs. 35.3%, $p < 0.01$). There were 3 common indications for intrauterine pressure catheter placement: documentation of adequate uterine contractions, timing of decelerations and amnioinfusion. The reasons for cesarean delivery are listed in Table III. There was no statistically significant difference between the groups ($p = 0.45$).

All 8 cases of extramembranous placement documented at cesarean delivery occurred in the transducer-tipped group. In 3 of these cases, the catheter was in the placenta (Table IV). Two of them revealed placental separation, with a blood clot at the insertion site.

One patient in the air-coupled group had a flash of blood-tinged fluid in the tubing of the catheter and was considered to have extramembranous placement. The catheter was replaced and functioned normally. This patient went on to deliver vaginally. There was no evidence of placental abruption on inspection of the placenta.

Secondary outcome variables are presented in Table IV. The only statistically significant difference between the groups was the higher rate of bleeding after insertion in the transducer-tipped group.

Because we were concerned that poor quality of contraction monitoring could have led to the increase in cesarean delivery in the transducer-tipped group, 2 independent, experienced, blinded observers were asked to review each contraction monitoring record for both an objective and subjective assessment of the monitoring. Percent signal detection was recorded for baseline uterine tonus, contraction frequency and contraction strength (peak millimeters of mercury). The amount of time that the signal was recorded for each of the variables was documented. A score of 1 was given for < 50%, 2 for between 60–70%, 3 for 71–80% and 4 for > 90% signal detection. There was no statistically significant difference for any of the variables tested (Table V).

We then asked the observers to subjectively assess the overall quality of the contraction monitoring for each record. This was recorded as a score of 1 for poor, 2 for average, 3 for good and 4 for excellent. The subjective mean overall quality was 2.9 ± 0.8 in the air-coupled group and 2.6 ± 1.0 in the transducer-tipped group ($p = 0.08$).

Because the experience of the physician who placed the catheters may have contributed to the differences between the groups, we compared the training level of those physicians. There was no statistically significant difference ($p = 0.57$) (Table VI). Furthermore, the training level was equally distributed among the extramembranously placed catheters (Table VII).

Discussion

Despite failure to demonstrate a reduction in the rate of cesarean deliveries or improvement in perinatal outcomes, internal monitoring of uterine contractions during labor is currently used in the management of 1 in 5 laboring women in the United States.[19,20] Indications include documentation of adequate labor, timing of fetal heart rate decelerations and amnioinfusion. Although generally regarded as a benign intervention, multiple complications have been associated with the use of intrauterine pressure catheters,[11] including perforation of fetal vessels,[12,13] umbilical cord entanglement,[14] uterine perforation[12] and an increase in infectious morbidity.

Recently there have been multiple reports of placental abruption soon after intrauterine pressure catheter placement[9,15,16] as well as descriptive series documenting a higher rate of extramembranous placement than previously thought.[17] This complication might be due in part to the stiffer transducer-tipped catheters, which, when inserted and advanced, can cause disruption of the placenta.

Table I *Demographic Characteristics of Women in the Trial*

Characteristic	Air-coupled IUPC (n = 120)	Transducer-tipped IUPC (n = 137)	p
Mean maternal age (yr)	29.6 ± 5.6	29.8 ± 5.8	0.78
Gravidity	1.9 ± 1.9	2.3 ± 2.4	0.25
Parity	0.6 ± 0.8	0.8 ± 1.1	0.56
Estimated gestational age (wk)	37.7 ± 6.4	38.9 ± 2.3	0.26
Duration of membrane rupture (h)	10.2 ± 5.2	14.8 ± 16.5	0.09
Oxytocin use (%)	79.1	67.2	0.48

IUPC = intrauterine pressure catheter.

Table II *Demographic Characteristics of Women with Cesarean Delivery*

Characteristic	Air-coupled IUPC (n = 41)	Transducer-tipped IUPC (n = 64)	p
Mean maternal age (yr)	29.4 ± 5.4	29.1 ± 6.4	0.78
Gravidity	2.3 ± 1.7	1.9 ± 1.5	0.69
Parity	1.1 ± 0.8	1.2 ± 0.7	0.78
Estimated gestational age (wk)	37.8 ± 6.3	38.9 ± 2.2	0.37
Duration of membrane rupture (h)	10.5 ± 9.7	11.8 ± 10.26	0.38
Illicit drug use (%)	11.1	8.8	0.77
Cocaine use (%)	3.3	0.98	0.53
Oxytocin use (%)	78.7	65.3	0.15
Tobacco use (%)	6.5	5.8	0.22
Cesarean delivery (%)	35.3	52.6	< 0.01

IUPC = intrauterine pressure catheter.

Table III *Reason for Cesarean Delivery*

Reason	Air-coupled IUPC (n = 41)	Transducer-tipped IUPC (n = 64)
Arrest of dilatation (%)	39.1	48.4
Arrest of descent (%)	14.6	15.6
Nonreassuring fetal heart rate pattern (%)	43.9	35.9
Other (%)	2.4	0

IUPC = intrauterine pressure catheter.

Table IV *Outcomes, by Catheter Type*

Characteristic	Air-coupled IUPC (n=41)	Transducer-tipped IUPC (n=64)	p
Bleeding after insertion (%)	9.3	22.8	0.02
Difficult insertion (%)	10.5	11.3	0.34
Removal for malfunction (%)	8.30	13.7	0.34
Extramembranous placement (%)	2.4	12.5	0.02
Placental separation (%)	0	3.1	0.58

IUPC = intrauterine pressure catheter.

We hypothesized that the rate of extramembranous placement would be lower with air-coupled pressure catheters as they have a smaller transducer and, due to the lack of electrical wires in the shaft, are more pliable. Because intrauterine pressure catheters may function normally in the extramembranous space, the true rate of extramembranous placement is unknown. We thought that the only accurate way to evaluate this was to conduct a randomized trial of the 2 catheter types and assess extramembranous placement at the time of cesarean delivery. As studies have documented similar accuracy between transducer-tipped and water-filled catheters,[21-23] although not universally,[24] we thought that such a study did not compromise patient care.

In this study, the overall rate of extramembranous placement was 7.9%. Moreover, all extramembranous placements documented at the time of cesarean delivery occurred in the transducer-tipped group, at a rate of 12.5%. Three of these extramembranously placed catheters were found in the placenta, with evidence of placental separation and a blood clot surrounding the pressure catheter in 2 patients. These findings may be corroborated by the higher rate of vaginal bleeding seen in the transducer-tipped group as compared to the air-coupled group. We did not observe a difference in the rate of clinical abruption or fetal distress when the 2 groups were compared.[4]

Table V *Objective Assessment of Intrauterine Pressure Catheters*

Variable	Air coupled	Transducer tipped	p
Baseline (mean)	2.1 ± 0.6	2.2 ± 0.4	0.97
Frequency (mean)	2.4 ± 0.8	2.4 ± 0.7	0.99
Strength (mean)	2.2 ± 0.5	2.1 ± 0.5	0.83

Table VI *Level of Training of Physicians Placing Catheters*

Level	Air-coupled group (%)	Transducer-tipped group (%)
PGY 1	33.6	27.1
PGY 2	7.8	12.8
PGY 3	18.1	12.8
PGY 4	10.8	12.8
Attending	0.9	3.0

PGY = postgraduate year.

As previously reported,[16] there was no association between sonographically documented placental position and extramembranous insertion. This was due most likely to wandering of the catheter during directed placement.

Directed extramembranous insertion of intrauterine pressure catheters in women with intact membranes has the advantage of delaying membrane rupture. It has been found to be similar to external uterine contraction monitoring in regard to contraction frequency and relative intensity.[25-27] However, these findings have not been universal[24]; in fact, these extramembranous catheters may not function equally well in women with membrane rupture. Commercially available intrauterine pressure catheters have not been designed to function extramembranously; resting tone and absolute pressure information is not available when catheters are applied extramembranously. Extramembranous insertion has never been shown to decrease any of the known complications of intraamniotic insertion of pressure catheters. Furthermore, amnioinfusion is not possible, and complications, such as placental abruption,[16-18] amniotic fluid embolism,[28,29] and uterine rupture[13,18] and perforation,[18] may be more likely when a catheter dissects in the extramembranous space.

Table VII *Level of Training and Extramembranous Catheter Placement*

Training level	No. of extramembranous placements
PGY 1	0
PGY 2	2
PGY 3	3
PGY 4	3
Attending	1
Total	9

PGY = postgraduate year.

Limitations of this trial include inability to blind physicians to group assignment due to the differences in construction of the catheters. Potential ascertainment bias for extramembranous placement may have occurred in the transducer-tipped group due to the higher cesarean section rate. There are several possible reasons for this increase in the cesarean rate: (1) the increased extramembranous rate of placement in the transducer-tipped group may have caused misinterpretation of the contraction monitoring record[30]; (2) placental separation, while not clinically apparent as vaginal bleeding, may have caused a subtle fetal heart or contraction disturbance, which may have prompted or delayed delivery; and (3) the increase in cesareans may reflect a random selection bias in that the women in the transducer-tipped group had membrane rupture 4.6 hours longer, though this failed to achieve statistical significance ($p = 0.09$). Systematic ascertainment bias, while possible, seems unlikely due to the lack of benefit to physicians placing the catheters and the randomized design of the study.

The thrust of this study was to examine the occurrence of extraamniotic placement of pressure catheters and not to examine the effect of the different catheters on the cesarean delivery rate. The small number of patients and the potential heterogeneity in the patient population make it difficult to come to a firm conclusion about the effect on cesarean delivery. While the overall rate of extramembranous placement was lower than our original estimate of 14%, we did not need to adjust our power calculation due to finding a significant difference in our primary outcome variable between the groups.

The strengths of this trial include: (1) its randomized design, (2) careful documentation of the placement of pressure catheters at cesarean delivery and (3) the fact that it was the only randomized trial to compare pressure catheters with different design characteristics and extramembranous placement.

Conclusion

Obstetricians should carefully consider the possible risks of extramembranous placement vs. the benefits of internal contraction monitoring before deciding to monitor, especially with a transducer-tipped catheter.

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